

**UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

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<b>CHILDREN’S HEALTH DEFENSE, et al.,</b>	:	
	:	
<b>Plaintiffs,</b>	:	
	:	
<b>V.</b>	:	<b>Case Number</b>
	:	<b>23-cv-4228-HB</b>
	:	
<b>CITY OF PHILADELPHIA, et al.,</b>	:	
<b>Defendants.</b>	:	
	:	

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**DEFENDANTS’ MOTION TO DISMISS THE COMPLAINT PURSUANT TO FED. R.  
CIV. P. 12(b)(1) AND 12(b)(6)**

Defendants the City of Philadelphia, the Philadelphia Department of Public Health, and Cheryl Bettigole, M.D., M.P.H., in her official capacity as Commissioner of the Department of Public Health (collectively, “City” or “Defendants”),<sup>1</sup> by and through their undersigned counsel, hereby file this Motion to Dismiss Plaintiffs’ Complaint, ECF No.1, pursuant to Fed. R. Civ. P. 12(b)(1) & (6).

Pursuant to Local Rule 7.1(c), Defendants hereby incorporate by reference the attached Memorandum of Law as though fully set forth at length herein.

The City respectfully requests that the Court grant its motion and dismiss the complaint with prejudice.

Respectfully submitted,

PHILADELPHIA LAW DEPARTMENT  
RENEE GARCIA, ACTING CITY SOLICITOR

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<sup>1</sup> Pursuant to 53 P.S. Section 16257, departments or agencies of the City of Philadelphia are not separate legal entities, and as such are not amenable to suit. All references to any Defendant in Plaintiffs’ filings refer to the City of Philadelphia.

Date: January 5, 2024

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**MEMORANDUM OF LAW IN SUPPORT OF THE CITY OF PHILADELPHIA’S  
MOTION TO DISMISS THE COMPLAINT PURSUANT TO FED. R. CIV. P. 12(b)(1)  
AND 12(b)(6)**

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## **I. INTRODUCTION**

In 2007, the Philadelphia Department of Public Health,<sup>1</sup> through its Board of Health, issued Regulations Governing the Immunization and Treatment of Newborns, Children, and Adolescents which govern minor consent to vaccination in Philadelphia. These Regulations were amended 2009 and consolidated 2019. The Regulations permit individuals aged 11 or older to consent to vaccination, “provided such person is capable of providing informed consent,” and although enacted fifteen years ago, the Regulations have not been challenged prior to this litigation.

On November 1, 2023, seven individual Plaintiffs and one associational plaintiff, Children’s Health Defense (“CHD”), filed a Complaint alleging that the Regulations violate federal and state law. Strikingly, the Complaint is devoid of any allegations of concrete or even speculative harm caused by the Regulations. The individual Plaintiffs who purport to bring claims on their own behalf and on behalf of their minor children allege neither that their minor children actually received vaccinations pursuant to the challenged policy nor that their minor children are likely to receive vaccinations under the policy, much less that any of that has occurred without a required person receiving a Vaccine Information Statement (“VIS”), a form provided under federal law to inform the vaccine recipient of the benefits and risks of a vaccine. Instead, they challenge the City’s Regulations on the basis that they are preempted by federal law, interfere with Plaintiffs’ rights as parents, and violate Pennsylvania non-delegation principles. But merely characterizing the Regulations, inferring a Policy, and alleging in

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<sup>1</sup> Pursuant to 53 P.S. § 16257, departments or agencies of the City of Philadelphia are not separate legal entities, and as such are not amenable to suit. All references to the Defendants will be deemed to refer to the City of Philadelphia.

conclusory fashion that the Philadelphia Department of Public Health's measures are unlawful is a far cry from standing to sue. The Complaint is also devoid of any allegations that a CHD member has or is likely to be harmed by the Regulations. As a result, Plaintiffs lack standing, do not have authority to invoke this Court's jurisdiction, and the Complaint should be dismissed without further analysis required.

Even if the Court were to reach the merits, the Complaint should be dismissed. The Philadelphia Department of Public Health's Regulations do not violate federal or state law, do not violate Plaintiffs' constitutional rights, and are well within the City's police power established by state law. Each Count in the Complaint fails to state a claim as a matter of law.

First, the Regulations are not preempted by federal law because there is no express or field preemption and the Regulations do not conflict with federal law. Federal law does not require parental notice when a minor may consent to treatment. Even if it did require such notice, the Regulations do not conflict with such a requirement, but provide separate, supplemental notice requirements regarding VIS and emergency authorization information. Because there is no conflict with federal law, the Regulations are not preempted.

Second, the Regulations do not violate Plaintiffs' constitutional rights to make decisions about their children's upbringing. As the District Court for the District of Columbia expressed in addressing this very issue, "courts find a violation of the parental liberty interest in directing the affairs of their children only when the behavior of the state actor compelled interference in the parent-child relationship." *Booth v. Bowser*, 2022 WL 2111561, at \*2 (D.D.C. Mar. 24, 2022) (citing *Anspach v. Philadelphia*, 503 F.3d 256, 262 (3d Cir. 2007)). There is no compelled interference present here and this claim fails as a matter of law.



Third, and lastly, the Regulations do not violate Pennsylvania law or constitute an unlawful delegation of legislative power from the General Assembly to the City. As we explain below, the City has broad regulatory powers under Pennsylvania’s Home Rule Act and the Regulations do not violate any provision of Pennsylvania law.

For these reasons and as explained further below, this Court should dismiss the Complaint for lack of jurisdiction. In addition, to the extent this Court believes further consideration is warrant, it should also dismiss the Complaint for failure to state a claim upon which relief may be granted.

## II. RELEVANT FACTS<sup>2</sup>

The Philadelphia Department of Public Health (“Department”) promulgated “Regulations Governing the Immunization and Treatment of Newborns, Children and Adolescents,” (“Regulations”) effective August 27, 2007, through the Philadelphia Board of Health. Compl., ¶ 4 & Ex. 1 to Compl. (attached hereto as **Exhibit A**).<sup>3</sup> The Regulations were amended effective April 6, 2009, attached hereto as **Exhibit B**,<sup>4</sup> and again on July 19, 2019, attached hereto as **Exhibit C**.<sup>5</sup> The 2019 Regulations provide, in relevant part:

MEDICAL EVALUATION, IMMUNIZATION, AND TREATMENT OF  
MINORS

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<sup>2</sup> Defendants accept the allegations in Plaintiffs’ Complaint as true for the purposes of this Motion only.

<sup>3</sup> <https://www.phila.gov/media/20181010160156/Regs-Governing-the-Immunization-and-Treatment-of-Newborns-Children-and-Adolescents-08272007.pdf>.

<sup>4</sup> <https://www.phila.gov/media/20181010160151/Amendment-to-Regs-Governing-the-Immunization-and-Treatment-of-Newborns-Children-and-Adolescents-04062009.pdf>.

<sup>5</sup> <https://www.phila.gov/media/20190716120557/BOH-School-and-Childcare-Immunization-Regulations-Consolidated-July-19-2019.pdf>.

(a) Minor's Consent to Examination and Treatment. A person between the ages of 11 and 18 may give consent, without the approval or consent of another person, for medical and other health examination, treatment and services to determine the presence of or to treat a sexually transmitted disease and any other disease, infection or condition reportable pursuant to the Disease Prevention and Control Law of 1955 and the regulations adopted thereunder, provided such person is capable of providing informed consent. The health care provider may not be sued or held liable for implementing appropriate diagnostic measures or administering appropriate treatment to the minor if the minor has consented to such procedures or treatment.

(b) Minor's Consent to Immunization. A person between the ages of 11 and 18 may authorize his or her own immunization, without the approval or consent of another person, to prevent occurrence of a reportable disease, infection, or condition, provided such person is capable of providing informed consent. A parent or guardian does not need to be present at the time the vaccine is administered. Written consent by the minor is not required, but documentation that the vaccine information statement (VIS) was provided to the vaccine recipient, and the publication date of the VIS, is required. The health care provider may not be sued or held liable for providing such immunization to the minor if the minor has consented to such procedures or treatment.

Ex. C at 6 (PDF p. 8).

On May 14, 2021, the Department issued the "Emergency Regulation for the Control and Prevention of COVID-19 Supplementing the Regulation Governing the Immunization and Treatment of Newborns, Children, and Adolescents (Vaccine Information Statements)" ("Emergency Regulation"). Emergency Regulation attached hereto as **Exhibit D**. The Emergency Regulation provides, in relevant part, that "the Emergency Use Authorization Fact Sheet for Recipients and Caregivers for a COVID-19 vaccine authorized by the [FDA] for use in persons of the age of the vaccine recipient . . . may be provided . . . when a Vaccine Information Statement does not exist for the COVID-19 vaccine being administered." Ex. D at 3.

Plaintiffs are parents of minor children and CHD, a California nonprofit corporation. Compl., ¶ 25. Plaintiffs Geoffrey, Roberts, and Parrillo are parents of minor children who live with them and are residents of Philadelphia. *Id.*, ¶¶ 26-28. Plaintiffs Zareczky, Morrissey,

Sadjian, and Huber are parents of minor children who reside with them and are residents of counties outside of Philadelphia. *Id.*, ¶¶ 29-32. Other than residing in or near Philadelphia, and the ages of their children, the individual Plaintiffs do not allege any other facts specific to them or their minor children. *See generally* Compl.

### III. LEGAL STANDARDS

A motion to dismiss for lack of standing is “properly brought pursuant to [Federal] Rule [of Civil Procedure] 12(b)(1), because standing is a jurisdictional matter.” *In re Schering Plow Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235, 243 (3d Cir. 2012) (quoting *Ballentine v. United States*, 486 F.3d 806, 810 (3d Cir. 2007)). Courts must first determine if the motion “presents a facial or factual attack.” *Id.* (citation omitted). Where defendants “contend that the [Complaint] lack[s] sufficient factual allegations to establish standing,” *id.*, they raise a “facial challenge” and courts “must only consider the allegations of the complaint and documents referenced therein and attached thereto, in the light most favorable to the plaintiff,” *id.* (quoting *Gould Elec. Inc. v. United States*, 220 F.3d 169, 176 (3d Cir. 2000)). Finally, the standard governing motions to dismiss pursuant to Rule 12(b)(6) applies. *Id.*

The applicable standard for a Rule 12(b)(6) motion is well-settled. Under this Rule, the Court should dismiss an action on a motion made before a responsive pleading is filed, when a complaint “fail[s] to state a claim upon which relief can be granted.” Fed. R. Civ. P. 12(b)(6). Courts undertake a three-step analysis in ruling on a motion to dismiss pursuant to Rule 12(b)(6):

**First**, the court must tak[e] note of the elements a plaintiff must plead to state a claim. **Second**, the court should identify allegations that, because they are no more than conclusions, are not entitled to the assumption of truth. **Finally**, where there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement for relief.

*Id.* (quoting *Santiago v. Warminster Twp.*, 629 F.3d 121, 130 (3d Cir. 2010)) (emphasis added) (internal quotations omitted). A complaint must “show” its “entitlement” to relief “with its facts.” *Id.* at 244 (quoting *Fowler v. UPMC Shadyside*, 578 F.3d 203, 211 (3d Cir. 2009)). The Court may also consider matters of public record such as legislative history, judicial documents, “letter decisions of government agencies, . . . and published reports of administrative bodies.” *Pension Ben. Guar. Corp. v. White Consol. Indus., Inc.*, 998 F.2d 1192, 1196-97 (3d Cir. 1993) (internal citations omitted). “[A] plaintiff’s obligation to provide the ‘grounds’ of his ‘entitle[ment] to relief’ requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.” *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007); *see also Ashcroft v. Iqbal*, 556 U.S. 662, 678-79 (2009) (stating that a Complaint must contain something more than “naked assertion[s]” devoid of “further factual enhancement.”).

#### IV. ARGUMENT

##### A. Plaintiffs Lack Standing

None of the individual Plaintiffs has standing for any of their claims because they fail to allege a concrete or particularized harm that is fairly traceable to the challenged Regulations. Nor do they allege an impending harm fairly traceable to the challenged Regulations. Indeed, the individual Plaintiffs do not allege *any* facts specific to them or their children. Their generalized grievance with the Regulations is insufficient to confer standing. Because the individual Plaintiffs fail to allege any harm at all, let alone concrete or imminent, particularized harm that is fairly traceable to the Regulations, they lack standing and cannot invoke the jurisdiction of this Court.

“Article III gives federal courts jurisdiction over ‘Cases’ and ‘Controversies.’ *Hartnett v. PSEA*, 963 F.3d 301, 305 (3d Cir. 2020) (citing U.S. Const. art. III, § 2, cl. 1). “[F]ederal courts can entertain actions only if they present live disputes, ones in which both sides have a personal

stake.” *Id.* (citing *Summers v. Earth Island Inst.*, 555 U.S. 488, 492–93 (2009)). “At the start of litigation, the burden rests on the plaintiff, ‘as the party invoking federal jurisdiction,’ to show its standing to sue.” *Id.* (quoting *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016)). “That requires showing injury in fact, causation, and redressability.” *Id.* (citing *Spokeo, Inc.*, 578 U.S. at 338).

“[A]n ‘injury in fact’ [is] an invasion of a legally protected interest which is (a) concrete and particularized; and (b) actual or imminent, not conjectural or hypothetical.” *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992) (cleaned up). “Allegations of *possible* future injury are not sufficient”; the injury must be “*certainly impending*.” *Clapper v. Amnesty Int’l USA*, 568 U.S. 398, 409 (2013) (cleaned up) (emphasis in original). “For an injury to be ‘particularized,’ it must affect the plaintiff in a personal and individual way.” *Spokeo, Inc.*, 578 U.S. at 339 (internal quotations omitted). “A ‘concrete’ injury must be ‘de facto’; that is, it must actually exist.” *Id.* (citation omitted). “Article III standing requires a concrete injury even in the context of a statutory violation.” *Id.* at 341. “For that reason, [Plaintiff] could not, for example, allege a bare procedural violation, divorced from any concrete harm, and satisfy the injury-in-fact requirement of Article III.” *Id.* (citation omitted).

The instant Complaint is devoid of factual allegations of concrete, particularized harm to Plaintiffs or their minor children. For the individual Plaintiffs, in relevant part the Complaint only identifies each individual Plaintiff and avers that they have minor children and are in or in proximity to Philadelphia. *See generally* Compl., ¶¶ 26-32. Although the Complaint asserts that the Regulations violate the individual Plaintiffs’ rights, the grievance is wholly general and nowhere does it plead facts that connect the Regulations to any legally cognizable harm to Plaintiffs. For example, Plaintiffs do not allege that they object to their children receiving vaccines or that they are withholding consent for vaccination; they do not allege that their

children received any vaccine without parental consent or that their children received a vaccine without the parents receiving a VIS; and they do not allege—as speculative as it would be—that their children are likely to seek out a Health Department clinic for vaccination against their parents’ wishes or desire to receive vaccines at all. Moreover, for the Plaintiffs who reside *outside of Philadelphia*, the Complaint contains no facts alleging that their child might seek or receive a vaccine in Philadelphia without parental consent. In fact, the Complaint does not even allege a *single case* of a minor being vaccinated in Philadelphia without parental consent or over a parent’s objection under the challenged Regulations, and even if it did, such an occurrence would not give these Plaintiffs standing.

Put simply, the Complaint contains no allegations that confer standing on the individual plaintiffs. To challenge the Regulations, Plaintiffs “must demonstrate a realistic danger of sustaining a direct injury as a result of the [Regulations’] operation and enforcement.” *Babbitt v. United Farm Workers Nat’l Union*, 442 U.S. 289, 298 (1979) (citation omitted). Speculative allegations of possible future injury are insufficient to satisfy the requirements of Article III, *see, e.g., Clapper v. Amnesty Int’l USA*, 568 U.S. at 409; *Thorne v. Pep Boys Manny Moe & Jack Inc.*, 980 F.3d 879, 893-94 (3d Cir. 2020) (finding plaintiff’s alleged, future harm from defendant’s failure to register her tires too speculative to confer standing), yet the lack of standing for the individual Plaintiffs here is even more stark because there are absolutely no alleged facts of any past or future injury to any of the individual Plaintiffs, no matter how speculative. And courts cannot and should not speculate about or embellish the Complaint to conclude that there is standing. *See Kamal v. J. Crew Group, Inc.*, 918 F.3d 102, 118 & n.10 (3d Cir. 2019) (declining to speculate about the effect of a similar—but additional—injury not raised in the second amended complaint on the standing analysis) (citing *Whitmore v. Arkansas*, 495

U.S. 149, 155-56 (1990) (“A federal court is powerless to create its own jurisdiction by embellishing otherwise deficient allegations of standing.”)); *Miccosukee Tribe of Indians v. Fla. State Athletic Comm’n*, 226 F.3d 1226, 1229–30 (11th Cir. 2000) (noting that the Court “should not speculate concerning the existence of standing, nor should [it] imagine or piece together an injury sufficient to give plaintiff standing when it has demonstrated none”).

Finally, the organizational plaintiff, CHD, fails to allege any facts at all that could support finding that it has associational standing. To establish standing in a case such as this, an association such as CHD must at minimum “make specific allegations establishing that at least one identified member ha[s] suffered or would suffer harm.” *New Jersey Physicians*, 653 F.3d 234, 241 (3d Cir. 2011) (quoting *Summers*, 555 U.S. at 498). CHD has not even attempted to satisfy this basic principle as the Complaint is devoid of reference to any of its members, much less an identified individual member, and also devoid of any specific allegations regarding any specific individual suffering cognizable harm. The Complaint does not establish that any member of CHD has suffered harm and therefore CHD does not have standing. *See, e.g., Chamber of Com. for Greater Philadelphia v. City of Philadelphia*, No. CV 17-1548, 2017 WL 11544778, at \*4 (E.D. Pa. May 30, 2017)

The individual Plaintiffs provide no factual allegations of harm to them or their children and CHD provides no factual allegations of harm to any of its members or their children caused by the Regulations *at all*. “It is an established principle . . . that to entitle a private individual to invoke the judicial power to determine the validity of executive or legislative action he must show that he has sustained or is immediately in danger of sustaining a direct injury as the result of that action and it is not sufficient that he has merely a general interest common to all members of the public.” *Lujan*, 504 U.S. at 574-75 (quoting *Ex parte Levitt*, 302 U.S. 633, 634 (1937)).

Plaintiffs' Complaint states a generalized grievance that is insufficient to confer standing and, thus, insufficient to invoke the jurisdiction of this Court.

**B. Count I Fails to State a Claim Because Federal Law Does Not Preempt the Regulations**

Plaintiffs claim in Count I of the Complaint that the City's Regulations are preempted by the National Childhood Vaccine Injury Act ("NCVIA"), 42 U.S.C. §§ 300aa-1 to 300aa-34 .

Plaintiffs fail to state a claim of federal preemption because the NCVIA does not preempt the field of childhood vaccination and because the Regulations do not conflict with the NCVIA.

*1. The Legal Standards Governing Federal Preemption*

Principles of federal preemption arise from the Supremacy Clause of the United States Constitution, which provides that the laws of the United States "shall be the supreme Law of the Land." Federal courts have interpreted this clause to "invalidate[] any state law that 'interferes with or is contrary to federal law.'" *Pennsylvania v. Navient Corp.*, 967 F.3d 273, 287 (3d Cir. 2020) (quoting *Free v. Bland*, 369 U.S. 663, 666 (1962)).

There are three types of federal preemption: field preemption; conflict preemption; and express preemption. Field preemption occurs when Congress has manifested a clear intent to supersede state law in a field and where a federal statutory scheme leaves no room for state regulation. *Navient*, 967 F.3d at 287. The Third Circuit has found field preemption only "in limited circumstances." *Sikkelee v. Precision Airmotive Corp.*, 822 F.3d 680, 687 (3d Cir. 2016). Conflict preemption occurs "when a state law conflicts with federal law such that compliance with both state and federal regulations is impossible" or "when a challenged state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of a federal law." *Id.* "Express preemption applies where Congress explicitly preempts state law in the statutory language." *Navient*, 967 F.3d at 287.



Where a claim of federal preemption is brought challenging state or local regulations that exercise the police power, courts must begin with the presumption that Congress did not intend to preempt state regulation, because, “the historic police powers of the States” are “not to be superseded by [a] [f]ederal [a]ct unless that was the clear and manifest purpose of Congress.” *Bedoya v. Am. Eagle Express Inc.*, 914 F.3d 812, 817 (3d Cir. 2019) (quotations omitted). In accordance with this presumption, “[w]hen faced with two equally plausible readings of statutory text, [courts] ‘have a duty to accept the reading that disfavors preemption.’” *Bruesewitz v. Wyeth Inc.*, 561 F.3d 233, 240 (3d Cir. 2009), *aff’d sub nom* (quoting *Bates v. Dow Agrosciences*, 544 U.S. 431, 449 (2005)). In addition, “[c]ongressional intent is the ultimate touchstone of a preemption analysis.” *Sikkelee v. Precision Airmotive Corp.*, 822 F.3d 680, 687 (3d Cir. 2016). When determining whether state law is preempted, courts “look to the language, structure, and purpose of the relevant statutory and regulatory scheme.” *Id.*

## 2. *The NCVIA Does Not Occupy the Field of Childhood Vaccination*

The Complaint alleges perfunctorily that in enacting the NCVIA, Congress manifested a clear intent to “occupy the field of law as to the administration of childhood vaccinations.” Compl., ¶ 117. While it is unclear whether Plaintiff is basing Count I on a theory of field preemption, such a claim fails here because the language, structure, and purpose of the NCVIA do not manifest an intent to occupy the entire field of vaccine administration. Further, the NCVIA leaves room for state and local regulation of administration of vaccines.

First, the stated purpose of the NCVIA is “to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines” through establishment of a “National Vaccine Program” and a “National Vaccine Injury Compensation Program.” 42 U.S.C.A. § 300aa-1. The NCVIA was enacted following years of instability and shortages in the vaccine market. *See Bruesewitz v. Wyeth LLC*,

562 U.S. 223, 226–28 (2011). “To stabilize the vaccine market and facilitate compensation, Congress enacted the NCVIA in 1986. The Act establishes a no-fault compensation program designed to work faster and with greater ease than the civil tort system.” *Id.* (internal quotation marks omitted). The NCVIA also established a system for providing information regarding benefits and risks of vaccines, as well as notice of the availability of the NCVIA’s compensation program, to vaccine recipients or their guardians. *See* 42 U.S.C. § 300aa-26. There is nothing in the language of the statutory scheme that suggests an intent to preempt the entire field of childhood vaccination law.

Further, the language of the NCVIA contemplates the federal agency coordinating with and providing assistance to states and localities in the administration of vaccines: “The Director of the Program shall, through the plan issued under section 300aa-3 of this title, coordinate and provide direction to the Centers for Disease Control and Prevention and ***assistance to States, localities, and health practitioners*** in the distribution and use of vaccines, including efforts to encourage public acceptance of immunizations and to make health practitioners and the public aware of potential adverse reactions and contraindications to vaccines.” 42 U.S.C. § 300aa-2 (emphasis added). This language contradicts Plaintiffs’ unsupported claim that Congress intended to completely supplant all state and local regulation of childhood vaccination. This is particularly clear as the local regulations at issue here—the City’s Regulations—are an exercise of traditional police power in the area of disease control and prevention.<sup>6</sup>

Finally, the inclusion of narrow express preemptions provision in the NCVIA demonstrates that Congress did not intend to preempt the entire subject matter of childhood

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<sup>6</sup> An interpretation that the CDC has adopted. *See* <https://www.cdc.gov/vaccines/hcp/vis/about/vis-faqs.html>.

vaccinations. 2 U.S.C. § 300aa-22(b)(1), (c). The NCVIA expressly provides that “[n]o State may establish or enforce a law which prohibits an individual from bringing a civil action against a vaccine manufacturer for damages for a vaccine-related injury or death if such civil action is not barred by this part.” 42 U.S.C. § 300aa-22 (titled “Preemption”). The NCVIA also expressly preempts claims for damages from vaccine injury in state court over \$1,000. *Id.* § 300aa-11. That it contains these specific provisions but does not expressly preempt other regulations related to childhood vaccination is further evidence that Congress did not intend to preempt the entire field of childhood vaccine administration. “The existence of an express pre-emption provision tends to contradict any inference that Congress intended to occupy a field broader than the statute's express language defines.” *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 547 (1992) (Scalia, J., concurring in part and dissenting in part).

### 3. *The Regulations Do Not Conflict With the NCVIA*

The Complaint alleges that the Regulations conflict with Section 300aa-26(d) of the NCVIA, which provides for distribution of vaccine information as follows:

[E]ach health care provider who administers a vaccine set forth in the Vaccine Injury Table shall provide to the legal representatives of any child or to any other individual to whom such provider intends to administer such vaccine a copy of the information materials developed pursuant to subsection (a), supplemented with visual presentations or oral explanations, in appropriate cases. Such materials shall be provided prior to the administration of such vaccine.

42 U.S.C. § 300aa-26(d). Plaintiff's conflict preemption claim fails.

The word “child” in the context of Section 300aa-26(d) can and should be interpreted to exclude minors who qualify to provide consent for immunization under the City's Minor Consent Policy. The term “child” is not defined in the NCVIA. “When a term is undefined, we give it its ordinary meaning.” *United States v. Santos*, 553 U.S. 507, 511 (2008). “Child,” however, is a word that means different things in different contexts. Merriam-Webster, for

example, contains multiple definitions of the word “child,” including “a young person especially between infancy and puberty,” “a person not yet of the age of majority,” “a son or daughter of human parents.” See <https://www.merriam-webster.com/dictionary/child>. When a word in a federal statute is capable of several meanings, it should be construed to “avoid the giving of unintended breadth to the Acts of Congress.” *Jarecki v. G. D. Searle & Co.*, 367 U.S. 303, 307 (1961). This is especially so when an overly broad interpretation would have the effect of preempting a state or local exercise of the police power. *Bruesewitz v. Wyeth Inc.*, 561 F.3d 233, 240 (3d Cir. 2009), *aff’d* 562 U.S. 223 (2011) (“When faced with two equally plausible readings of statutory text, [courts] ‘have a duty to accept the reading that disfavors preemption.’”). The title, purpose, and structure of the NCVIA provide additional contextual evidence that “child,” as used in the statute, is intended to refer to the recipients of childhood vaccines. The term “child” should not be read, as Plaintiffs insist, to impliedly—and drastically—reshape the law concerning the age of consent to medical care, for “Legislatures do not hide elephants in mouseholes.” *Gov’t Emps. Ret. Sys. of Virgin Islands v. Gov’t of Virgin Islands*, 995 F.3d 66, 98 (3d Cir. 2021). In accordance with these well-established principles of statutory interpretation, the Court should read “child” in NCVIA Section 300aa-26(d) to not include older minors whom state or local law allow to provide medical consent for immunization.<sup>7</sup>

This is the approach taken by the CDC, which has provided guidance on how the word “child” in Section 300aa-26(d) should be interpreted. In its FAQ regarding Vaccine Information Statements under the NCVIA, the CDC published the following question and answer:

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<sup>7</sup> Indeed, setting aside the specific nomenclature of “child,” the Complaint at Paragraph 61 recognizes that ‘minor’ as it is used under Pennsylvania law is subject to different meanings as it notes different ages at which individuals may be able to provide consent or subject to operations of Law.

How do we determine when a VIS must be given to a “legal representative” rather than to the patient? For example, if an 18-year old is considered a child, would it be illegal to give a VIS to him or her directly, as opposed to a parent or guardian?

A: The National Childhood Vaccine Injury Act does not define a “child” for purposes of the Act. “Legal representative” is defined as “a parent or an individual who qualifies as a legal guardian under State law.” *A reasonable interpretation is that State law, and specifically the State’s medical consent law, should be deferred to for purposes of defining who is a minor.* For example, if an 18 year old can consent to immunization under a State’s law, that 18 year old is the person who should be provided a copy of the VIS.

VIS Frequently Asked Questions, *available at* <https://www.cdc.gov/vaccines/hcp/vis/about/vis-faqs.html> (last visited \_\_\_\_\_) (emphasis added).

Under Philadelphia law, as set forth in the Regulations, young people aged 11 through 18 may provide medical consent to receive an immunization if they are capable of providing informed consent. As discussed further below, the Regulation is authorized by, and entirely consistent with, Pennsylvania law. Therefore, under the CDC’s guidance, the provision of a VIS to the vaccine recipient alone, were that to occur, would comply with the requirements of Section 300aa-26(d) of the NCVIA.<sup>8</sup>

For all of these reasons, Count I should be dismissed for failure to state a claim in accordance with Rule 12(b)(6).

C. This Court Should Dismiss Plaintiffs’ Constitutional Claim—That the Regulations Deprive Them of Their Right to Raise Their Children—Because the Regulations Do Not Coerce Children to Get Vaccinated.

In Count II, Plaintiffs claim that the Regulations deprive them of “their fundamental right to direct the upbringing of their children.” Compl., ¶¶ 123-127. However, as the *Booth* Court correctly explained when addressing the identical claim, “courts find a violation of the parental liberty interest in directing the affairs of their children only when the behavior of the state actor

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<sup>8</sup> It is worth noting that the VIS is not an informed consent form and providing it to a patient or a parent—standing alone—does not indicate informed consent.

compelled interference in the parent-child relationship.” *Booth*, 2022 WL 2111561, at \*2 (emphasis original). As we now explain, because there is no compelled interference—children have the choice to get vaccinated and the choice to discuss the issue with their parents—there is no constitutional deprivation.

The Third Circuit held in *McCurdy v. Dodd*, 352 F.3d 820 (3d Cir. 2003), that, “in § 1983 cases grounded on alleged parental liberty interests, [the Court] is venturing into the murky area of unenumerated constitutional rights,” *id.*, or the substantive component of due process. The substantive component of due process prohibits the government from infringing upon fundamental rights and liberty interests unless the infringement is narrowly tailored to serve a compelling state interest. *Reno v. Flores*, 507 U.S. 292, 302 (1993).

However, because the “contours of legal concepts such as liberty interests and fundamental rights are amorphous and indistinct,” this Court has further cautioned that addressing a substantive due process claim demands “scrupulous attention to the guideposts that have previously been established.” *McCurdy*, 352 F.3d at 826. Therefore, the Supreme Court has mandated that the alleged due process right at issue in a substantive due process case must be identified “carefully and precisely.” *Id.* Plaintiffs cannot do so here.

In *McCurdy*, for example, this Court rejected the invitation to recognize the parental liberty interest as an absolute right to the “the companionship, care, custody, and management of his or her children,” in spite of the Supreme Court’s explicit use of this language to describe the parental liberty interest in *Stanley v. Illinois*, 405 U.S. 645, 646 (1972). *See* 352 F.3d at 827. *McCurdy* rejected the plaintiff father’s claim that the City of Philadelphia and some of its employee police officers had unconstitutionally deprived him of his parental liberty interest in the companionship of his adult child when those officers used unconstitutionally excessive force

to kill his son. *McCurdy* found that in spite of the broad language used in cases that have recognized the parental liberty interest, that interest is limited to situations in which the government is interfering with decisions regarding the care, custody or control of a minor child. 352 F.3d at 826-27.

In *Anspach*, 503 F.3d at 262, the Court specifically held that the parental liberty interest exists “only where the behavior of the state actor compelled interference in the parent-child relationship.” There, the City provided emergency contraception to a minor without parental consent, but the Court held that there was no infringement of a constitutional right to parent because “Plaintiffs cannot maintain a due process violation when the conduct complained of was devoid of any form of constraint or compulsion.” *Id.* at 264. The City health clinic (where the minor received the contraception) exerted no authority over her, and it did not instruct her to avoid contacting her parents. The minor had every opportunity to contact her parents, so the City did not violate Plaintiffs’ parental rights.

Similarly, there is no coercion here to get a vaccine. The Regulations do not require vaccinations and they do not prevent minors from discussing the issue with their parents. Accordingly, because Plaintiffs alleged no interference with Plaintiffs’ right to raise their children, there is no constitutional deprivation (in addition to the lack of standing). *See id.* at 266 (“concluding that parents failed to state a claim where the allegations were “not that the state actors interfered with the Anspachs as parents; rather, it is that the state actors did not assist the Anspachs as parents or affirmatively foster the parent/child relationship.”) (emphasis original).

Notably, the District Court in *Booth* relied upon *Anspach* to reach the exact same result. As that Court explained: “The MCA [D.C. Minor Consent Act] does not order the District—or anyone else—to vaccinate Plaintiffs’ children. The children must decide to get vaccinated. True,

the MCA facilitates children’s vaccination. But it does not command it. And although a state cannot actively intervene in a parent-child relationship, there is no constitutional requirement that the District foster that relationship.” *Booth*, 2022 WL 2111561, at \*1 (emphasis original).<sup>9</sup>

Accordingly, this Court should dismiss Plaintiffs’ constitutional claim for deprivation of their parental rights.<sup>10</sup>

D. This Court Should Dismiss Plaintiffs’ State-Law Non-Delegation Claim Because the Regulations Are Authorized by and Consistent with Pennsylvania Law.

In Count III, Plaintiffs claim that the Regulations are impermissible because the City has “not been delegated authority from the General Assembly to establish laws or regulations that contradict the laws of the Commonwealth.” Compl., ¶ 130. They claim that, because the City exceeded its allegedly “limited grant” of authority by promulgating Regulations that contradict state law, the Court should prevent the Regulations’ enforcement. Compl., ¶ 129. However, the City has broad powers of regulation where (as here) its Regulations are consistent with the General Assembly’s laws.

As a preliminary matter, if the Court dismisses Plaintiffs’ federal claims, it may “decline to exercise supplemental jurisdiction” over the remaining state law claims. *See, e.g., Murphy v. Int’l Druidic Soc.*, No. 13-511, 2013 WL 3091277, \*6 (E.D. Pa. June 20, 2013) (citing 28 U.S.C.

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<sup>9</sup> While the City does not agree with all aspects of the Booth court’s reasoning, the cited provisions are accurate statements of federal law.

<sup>10</sup> In arguing to the contrary, Plaintiffs (Compl., ¶¶ 99-105) rely upon cases like *Troxel v. Granville*, 530 U.S. 57 (2000), and *Parham v. J. R.*, 442 U.S. 584 (1979), for the proposition that the Constitution protects the parental right to raise one’s children. But, as the *Booth* Court succinctly explained: “all these cases are distinguishable. In each, the state’s conduct was invasive. The MCA, on the other hand, is permissive, not prescriptive. Thus, none of these cases supports Plaintiffs’ claim.” *Booth*, 2022 WL 2111561, at \*3.



§ 1367(a), (c)(3); *Borough of W. Mifflin v. Lancaster*, 45 F.3d 780, 788 (3d Cir. 1995)). Because there “is no judicial economy in trying the state claims here,” the Court should dismiss them. *Id.*

The City of Philadelphia has extensive powers of regulation, pursuant to the First-Class City Home Rule Act, Act of April 21, 1949, P.L. 665, 53 P.S. § 13101, et seq. (“the Home Rule Act”); and “may legislate as to municipal functions as fully as could the General Assembly.” *Warren v. Philadelphia*, 115 A.2d 218, 221 (Pa. 1955) (upholding City rent control ordinance). The Pennsylvania Supreme Court has instructed that such grants of home rule power are to be liberally construed in favor of the municipality, and it “cannot stress enough that a home rule municipality’s exercise of its local authority is not lightly intruded upon, with ambiguities regarding such authority resolved in favor of the municipality.” *Nutter v. Dougherty*, 938 A.2d 401, 414 (Pa. 2007).

Beyond the general grant of authority under the First-Class City Home Rule Act, the General Assembly has also expressly authorized local health authorities to regulate health matters including through vaccination against communicable disease, as discussed below. *See, e.g.*, 35 P.S. § 521.3(a); 35 P.S. § 521.16. Moreover, the City’s immunization Regulations are authorized under Charter § 5-300, governing duties and powers of the Department of Public Health. *See Dep’t of Licenses & Inspections, Bd. Of License & Inspection Rev. v. Weber*, 147 A.2d 326, 330 (Pa. 1959) (“the City of Philadelphia, under the Home Rule Charter of 1951, is armed with police power to cope with problems of health”). Thus, the City has the broad power to enact measures to health and disease-prevention measures “as fully as could the General Assembly.” Plaintiffs’ assertion that the City only has a “limited grant” of authority is simply wrong.

Of course, where the City's Regulations conflict with state law, they may be preempted. *Middletown Twp. V. Benham*, 523 A.2d 311, 313 (Pa. 1987); *see also* 53 P.S. § 13133(b), (c). However, the standard for finding preemption under Pennsylvania law is quite high: "[p]reemption . . . is the exception and not the rule." *Nutter*, 938 A.2d at 406. Courts only find conflict preemption where the local enactment and the state law are "irreconcilable." *Bethlehem v. Marcincin*, 515 A.2d 1320, 1326 (Pa. 1986). The Pennsylvania Supreme Court has limited such irreconcilability to situations where "simultaneous compliance with both the local ordinance and the state statute is impossible." *Hoffman v. Cambria Cty.*, 32 A.3d 587, 594 (Pa. 2011).

The City can certainly meet that deferential standard here. Far from limiting the City's ability in the realm of public health, the General Assembly has issued multiple grants of authority that make clear the City has the power to adopt ordinances and regulations related to public health issues, including immunization (provided those local rules do not conflict with Commonwealth law or regulations). For example, under the Disease Control and Prevention Law of 1955 ("DCPL"), "[l]ocal boards and departments of health shall be primarily responsible for the prevention and control of communicable and non-communicable disease, including disease control in public and private schools, in accordance with the regulations of the board and subject to the supervision and guidance of the [State Department of Health]." 35 P.S. § 521.3(a) (emphasis added); *see also* 35 P.S. § 521.16(c) ("Municipalities which have boards or departments of health . . . may enact ordinances or issue rules and regulations relating to disease prevention and control, which are not less strict than the provisions of this act or the rules and regulations issued thereunder by the board."); *Pennsylvania Rest. & Lodging Ass'n v. City of Pittsburgh*, 211 A.3d 810, 828 (Pa. 2019) ("We find in the DPCL a holistic scheme that, for

purposes of disease prevention and control, favors local regulation as informed by the expertise of a dedicated local board or department of health over state-level regulation, and correspondingly allows local lawmakers to impose more stringent regulations than state law provides.”). Accordingly, the General Assembly has specifically authorized the Health Department to adopt regulations regarding public health and disease prevention.

Further, the City’s regulations do not irreconcilably conflict with any General Assembly pronouncements. In claiming such a conflict, Plaintiffs rely most prominently on 35 P.S. § 10101: “Any minor who is eighteen years of age or older, or has graduated from high school, or has married, or has been pregnant, may give effective consent to medical, dental and health services for himself or herself, and the consent of no other person shall be necessary.” Plaintiffs argue that this provision states that “individuals under eighteen generally may not receive medical treatment absent parental consent.” Compl., ¶ 60. But that is untrue.

By way of background, the General Assembly has generally defined a minor as a “person under the age of 21 years.” 1 Pa. C.S. § 1991. In that context, section 10101 merely provides one broad exception to the general 21-year-old rule. It states that individuals 18 and over do not need consent (and hence are not minors) for purposes of any medical or health services. The provision is silent as to individuals under 18, and most certainly does not state that individuals under 18 must have parental consent for those services. For individuals under 18, section 10101 leaves open the possibility that either the General Assembly or an authorized local authority, in this case, the City, would allow young people to consent to their own medical care in specific situations.

Indeed, there are many narrowly tailored situations where the General Assembly has allowed individuals under 18 to give consent to medical and health services, regardless of

parental consent, in particular contexts. For example, section 10101 exempts minors who are married, high school graduates, or were previously pregnant. The Commonwealth also empowers any minor who is pregnant, has a venereal disease, or has a reportable disease under the DCPL to give consent. 35 P.S. § 10103. And a minor who suffers from use of a controlled or harmful substance may consent to the furnishing of medical care or counseling. 71 P.S. § 1690.112; *see also Com. v. Nixon*, 761 A.2d 1151, 1157 (Pa. 2000) (Cappy, J. concurring) (“The Pennsylvania legislature... has rendered the authority of parents to speak for their minor child with respect to health care less than absolute in certain circumstances, by enacting several statutes that allow minors to speak for themselves.”); *cf. Parents United For Better Sch., Inc. v. Sch. Dist. of Philadelphia Bd. of Educ.*, 148 F.3d 260, 269 (3d Cir. 1998) (“it seems absurd for the legislature to allow minors to consent to treatment once they are pregnant or infected with a sexually transmitted disease, but forbid them to obtain contraceptives to prevent those conditions without parental consent.”).

By adopting the Regulations to allow for consent by young people age 11 to 18, the City simply expanded on the list of limited exceptions that the General Assembly has established for medical consent by minors. There is no Commonwealth law that generally prohibits people under age 18 from consenting to vaccination for communicable diseases and the City acted well within its authorized police powers in choosing to do so.

Section 10101 creates a baseline rule that individuals 18 and over do not need parental consent in any healthcare or medical setting, but the General Assembly and the City are free to provide additional specific examples where younger individuals do not need parental consent

(whether those examples be where the individual is married, or the individual has an STD, or, as here, the individual wants to get a prophylactic vaccine).<sup>11</sup>

**V. CONCLUSION**

Defendant the City of Philadelphia respectfully requests that this Court dismiss the Complaint with prejudice for lack of jurisdiction and failure to state a claim upon which relief may be granted.

Respectfully submitted,

PHILADELPHIA LAW DEPARTMENT  
RENEE GARCIA, ACTING CITY SOLICITOR

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<sup>11</sup> Plaintiffs (Compl., ¶ 66) are correct that the General Assembly has limited pharmacists from vaccinating minors without parental consent. 63 P.S. § 390-9.2(a)(5). But the Regulations do not speak to just pharmacists but to all medical providers. Indeed, the fact that the state legislature was specific in requiring parental consent from a pharmacist, but has been silent with respect to other authorized providers such as doctors, is evidence that such consent is not required for those other providers.

**UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

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**CHILDREN’S HEALTH DEFENSE, et  
al.,**

**Plaintiffs,**

**V.**

**CITY OF PHILADELPHIA, et al.,**

**Defendants.**

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**Case Number  
23-cv-4228-HB**

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**ORDER**

AND NOW, this \_\_\_\_\_ day of \_\_\_\_\_, 2024, upon consideration of Defendants’ Motion to Dismiss Plaintiffs’ Complaint, any response in opposition, and the oral arguments of the parties, if any, it is hereby ORDERED that Defendants’ Motion to Dismiss Plaintiffs’ Complaint is GRANTED. All claims by the Plaintiffs against the Defendants are DISMISSED WITH PREJUDICE.

IT IS SO ORDERED.

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Harvey Bartle III, J.

**UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

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**CHILDREN’S HEALTH DEFENSE, et  
al.,**

**Plaintiffs,**

**V.**

**CITY OF PHILADELPHIA, et al.,**

**Defendants.**

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**Case Number  
23-cv-4228-HB**

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**CERTIFICATE OF SERVICE**

I, Ryan B. Smith, hereby certify that on January 5, 2024, a true and correct copy of the foregoing Motion to Dismiss Plaintiffs’ Complaint, Memorandum of Law, and Proposed Order were served via the Court’s electronic filing system on counsel for Plaintiffs.

DATE: January 5, 2024

By: /s/ Ryan B. Smith  
Ryan B. Smith  
Deputy City Solicitor